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VI. 510 K Summary for Brixton Barrier Products

I. Submitted by

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2. Device Name: Brixton Infection Control Barrier

Classification Name: Dental Handpiece and Accessory

FDA Classification: Class II per 21 CFR 872.4200

3. Predicate Devices: Filmtech, Inc. claims substantial equivalence for their Brixton Infection Control Barrier to **K900093** Dentsply International Inc.'s Dispos-a-Shield Infection Control Barrier and **K952234** Cottrell, Ltd.'s Barrier All Film.

4. Intended Use: Brixton Infection Control Barrier is intended as a single use, transparent plastic, disposable, nonsterile barrier that will help reduce gross contamination and provide equipment surface protection for devices used within the dental/ clinical treatment setting. Brixton Infection Control Barriers are available in an assortment of sizes and shapes, designed to accommodate the following types of equipment:

* Light Handles

- * Chairs
- * Headrests
- * Air and Water Syringe sleeves (ties included)
- * Stools
- * X-Ray Heads
- * Trays

5. Device Description/ Technological Characteristics

The Brixton Infection Control Barrier manufactured by Filmtech, Inc. is intended as a single use, disposable, transparent, polyethylene plastic equipment cover that will help provide surface protection and reduce cross contamination of equipment used in the dental/ clinical setting. The barriers are available in a variety of sizes and shapes, dispensed in boxes containing 200, 250 or 500 covers.

6. Conclusion

The Brixton Infection Control Barrier has no significant difference that will alter the effect or raise new issues of safety and effectiveness; has substantially equivalent technological and performance characteristics as the predicate devices; and raises no new types of safety or effectiveness questions. All characteristics of the Brixton Infection Control Barriers support the finding of substantial equivalence.